IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

The University of Utah **Plaintiff,**	)	**COMPLAINT**
v.	)	**Civil Action No.**
	)	**JURY TRIAL DEMANDED**
Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., a corporation organized under the laws of Germany; **Max-Planck-Innovation GmbH**, a corporation organized under the laws of Germany; **Whitehead Institute for Biomedical Research**, a Delaware corporation; **Massachusetts Institute of Technology**, a Massachusetts corporation; **University of Massachusetts,** a Massachusetts corporation; and **Alnylam Pharmaceuticals, Inc.,** a Delaware corporation. **Defendants.**	)	

COMPLAINT

Plaintiff, The University of Utah, by and through its attorneys, Pepper Hamilton LLP, for its Complaint against Defendants, Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V., Max-Planck-Innovation GmbH, Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology, University of Massachusetts, and Alnylam Pharmaceuticals, Inc., states as follows:

THE PARTIES

1. Plaintiff, The University of Utah is an organization existing under the laws of the State of Utah with a principal place of business at 201 Presidents Circle, Room

201, Salt Lake City, Utah, 84112. The University of Utah will be referred to herein as the "University."

2. On information and belief, defendant, Max-Planck-Gesellschaft zur Forderung der Wissenschaften E.V. ("Max Planck Society"), is a corporation organized and existing under the laws of Germany with a principal place of business in Munich, Germany. The English translation of the corporation's full name is "Max Planck Society for the Advancement of Science." The Max Planck Society is engaged in the conduct of trade or commerce.

3. On information and belief, defendant Max-Planck-Innovation GmbH ("Max-Planck-Innovation"), formerly known as Garching Innovation GmbH, is a corporation organized and existing under the laws of Germany with a principal place of business in Munich, Germany. Max-Planck-Innovation is the technology transfer arm of Max Planck Society. Max-Planck-Innovation is engaged in the conduct of trade or commerce. Max Planck Society and Max-Planck-Innovation are collectively referred to herein as "Max Planck." On information and belief, Max Planck, conducts business in the Commonwealth of Massachusetts and has availed itself of its laws by filing the complaint titled, *Max-Planck et al. v. Whitehead Institute for Biomedical Research et al.*, 09-11116-PBS.

4. On information and belief, defendant Whitehead Institute for Biomedical Research ("Whitehead") is a Delaware corporation with a principal place of business in Cambridge, Massachusetts. Whitehead is engaged in the conduct of trade or commerce.

5. On information and belief, defendant Massachusetts Institute of Technology ("MIT") is a Massachusetts corporation with a principal place of business in Cambridge, Massachusetts. MIT is engaged in the conduct of trade or commerce.

6. On information and belief, defendant University of Massachusetts ("UMass") is a Massachusetts corporation with a principal place of business in Worcester, Massachusetts. UMass is engaged in the conduct of trade or commerce.

7. On information and belief, defendant Alnylam Pharmaceuticals, Inc. ("Alnylam") is a Delaware corporation, engaged in the conduct of trade or commerce, with a principal place of business in Cambridge, Massachusetts.

OTHER PERSONS AND THINGS MENTIONED IN THIS COMPLAINT

8. On information and belief, Thomas Tuschl is an individual working as an Associate Professor at Rockefeller University, and who serves on The Alnylam Scientific Advisory Board. Tuschl was a founder of Alnylam in 2002, and has been a shareholder since that time. At all times since then he has had an interest in the success of the company. Tuschl is one of the named inventors of the Tuschl I patent application referred to in this Complaint. He is also a named inventor of the Tuschl II patent applications and issued patents that are the subject of this Complaint.

9. On information and belief, Phillip Sharp is an individual residing in Massachusetts, working as an Institute Professor at the Koch Institute for Integrative Cancer Research at MIT, and who serves as a member of the Board of Directors of Alnylam, and on The Alnylam Scientific Advisory Board. He was a founder of Alnylam in 2002, and has been a shareholder since that time. At all times since then he has had an

interest in the success of the company. Sharp is one of the named inventors of the Tuschl I patent application referred to in this Complaint.

10. On information and belief, David Bartel is an individual residing in Massachusetts, working as a member of the Whitehead Institute and a Professor of Biology at MIT, and who serves on The Alnylam Scientific Advisory Board. He was a founder of Alnylam in 2002, and has been a shareholder since that time. At all times since then he has had an interest in the success of the company. Bartel is one of the named inventors of the Tuschl I patent application referred to in this Complaint.

11. On information and belief, Phillip Zamore is an individual residing in Massachusetts, working as the Gretchen Stone Cook Professor of Biomedical Sciences at the University of Massachusetts Medical School, and who serves on The Alnylam Scientific Advisory Board. He was a founder of Alnylam in 2002, and has been a shareholder since that time. At all times since then he has had an interest in the success of the company. Zamore is one of the named inventors of the Tuschl I patent application referred to in this Complaint.

12. On information and belief, Sayda Elbashir is an individual residing in Massachusetts, and working as Principal Scientist and Project Leader, Research in the Biology and Drug Discovery Department at Alnylam. She is a named inventor of the Tuschl II patent applications and issued patents that are the subject of this Complaint.

13. On information and belief, Winfried Lendeckel is an individual working at the Max Planck Institute for Biophysical Chemistry, a research institution operated by the Max Planck Society. He is a named inventor of the Tuschl II patent applications and issued patents that are the subject of this Complaint.

14. Drs. Andrew Z. Fire and Craig C. Mello won the 2006 Nobel Prize in Physiology or Medicine for their discovery of RNA interference in multicellular animals – gene silencing by double-stranded RNA.

15. A litigation involving several of the parties, individuals, and institutions mentioned in this Complaint, *Max-Planck et al. v. Whitehead Institute for Biomedical Research et al.*, 09-11116-PBS (the "*Whitehead* litigation"), is currently before this Court. A press release dated March 15, 2011, indicates that a settlement among the parties has been reached. The Max Planck Society, Max-Planck-Innovation, and Alnylam are each plaintiffs in the *Whitehead* litigation. Whitehead, UMass, and MIT are or have been defendants in the *Whitehead* litigation.

16. "Tuschl I" refers to a patent application filed with the United States Patent and Trademark Office ("USPTO") in March 2000. The named inventors are Drs. Tuschl, Zamore, Bartel, and Sharp. As discussed in ¶ 62 below, the University currently cannot pursue any relief with respect to the Tuschl I application.

17. "Tuschl II" refers to a family of patent applications filed in the European Patent Office and the USPTO, that are the subject of this Complaint. The U.S. Patents are: (1) U.S. Patent No. 7,056,704 (the "'704 Patent") (attached as Exhibit 1); and (2) U.S. Patent No. 7,078,196 (the "'196 Patent") (attached as Exhibit 2). The named inventors on the Tuschl II applications are Drs. Tuschl, Elbashir, and Lendeckel. Max Planck had been assigned the rights to the Tuschl II patents, and it, in turn, had exclusively licensed the Tuschl II patents to Alnylam. According to press reports, pursuant to the settlement in the *Whitehead* litigation, Whitehead, Max Planck, UMass,

and MIT will all be co-owners of the Tuschl II patent family, and UMass will be able to sublicense the Tuschl II patent family to Merck & Co.

JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, and 2201.

19. This Court also has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity among the parties exists, and the amount in controversy exceeds $75,000.

20. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (d).

FACTUAL ALLEGATIONS

Background

21. The University of Utah is Utah's oldest and largest institution of higher education and is a major research university, with research and training awards of $450,614,999 for the years 2009-2010. The University's research expenditures were the 67th highest in the nation in 2008, and the 58th highest for federal research expenditures. The University ranked 52nd highest in the nation for membership in the National Academy of Sciences, 50th for faculty awards, 51st for doctorates awarded, and 42nd for postdoctoral appointees. It was also responsible for the second highest number of startups in both 2006 and 2007—second only to MIT.

22. The University of Utah is engaged in the conduct of trade or commerce, by among other things, developing and licensing technology and patents invented by its faculty, incubating new companies based on University technology, and operating the University of Utah Hospital.

23. Dr. Brenda Bass is a Distinguished Professor at the University of Utah. She received her B.A. in Chemistry from Colorado College, and has been researching RNA biochemistry since she attended graduate school at the University of Colorado from 1980-1985. During graduate school she researched RNA splicing reactions with Dr. Thomas Cech, who received the Nobel Prize in 1989 for discovering ribozymes—RNA molecules that catalyze biological reactions. Her PhD work focused on ribozymes that cleave and ligate RNA, and she became intimately familiar with RNA biochemistry.

24. During her postdoctoral work conducted from 1985-1989 at the Fred Hutchinson Cancer Center in Seattle, Washington, Dr. Bass discovered an enzyme, called adenosine deaminase, that acts on RNA ("ADAR"). She also discovered that ADARs act on double-stranded RNA ("dsRNA"). This discovery marked where her studies, interest, and knowledge of dsRNA began. This work laid the foundation for her later discoveries and inventions, including those involved here.

25. In 1989, after her postdoctoral work, Dr. Bass became an Assistant Professor at the University of Utah in the Department of Biochemistry. She became an Associate Professor in 1995, and a Professor in 1999. In 2007, she became a Distinguished Professor. As a condition of her employment with the University, Dr. Bass agreed that the University would acquire and retain title to all inventions, discoveries, and improvements, including all patents and patent documents, made as a result of her employment or research, or created through the use of time, facilities, equipment or materials owned or paid by or through the University.

26. During the course of her career, Dr. Bass has been awarded numerous honors, including: a Pew Scholars Award; a David and Lucile Packard Fellowship; a

named Investigator at the Howard Hughes Medical Institute for 15 years; and election to the American Academy of Arts & Sciences. She is also an editorial board member of *RNA,* and was an editorial board member of *Science* from 2004-2007. (*See*, Curriculum Vitae of Dr. Brenda Bass, attached as Exhibit 3.)

27. Dr. Bass was a founding member of the RNA Society in 1993. She has been a committee chair and board member and was elected its president in 2007. Drs. Zamore, Sharp and Bartel are all members of the RNA Society. Dr. Tuschl has attended RNA Society meetings. The RNA Society is the leading organization for the study of RNA science. It is a collaborative body of scientists founded to "facilitate sharing and dissemination of experimental results and emerging concepts in RNA research." (www.rnasociety.org/membership) Further, the RNA Society "is an interdisciplinary, cohesive intellectual home for those interested in all aspects of RNA Science." (www.rnasociety.org/membership) It publishes its own journal, *RNA.*

The Inventions

28. Dr. Bass conceived the inventions of all of the issued claims of Tuschl II and at least some pending claims of Tuschl I well before any date asserted by the currently named inventors.

29. Dr. Bass reduced her inventions to practice well before any date asserted by the currently named inventors of Tuschl I and II. Dr. Bass, with the assistance of her post-doctoral fellow, Dr. Scott Knight, reduced to practice her conception that the RNAse III enzyme Dicer was the key agent of RNAi, and hence, that the resultant molecule would have, *inter alia*, a 3' overhang, by treating multicellular animals with dsRNA

corresponding to *C. elegans* Dicer (K12H4.8) well prior to any date asserted by the currently named inventors of Tuschl I and Tuschl II.

30. Dr. Bass conceived treating mammals, including humans, using dsRNA of 21-23 nucleotides with a 3' overhang well before any date asserted by the currently named inventors of Tuschl I and Tuschl II.

Chronology

31. As an Assistant Professor at the University Dr. Bass researched and analyzed dsRNA binding proteins. She identified a sequence in these proteins, known as a dsRNA binding motif, and searched various gene databases to identify genes that would produce proteins with this dsRNA binding motif.

32. In the course of her search, Dr. Bass identified the *C. elegans* gene, K12H4.8, that is now known to produce the RNAse III enzyme colloquially known as "Dicer." As far back as 1993, Dr. Bass understood that Dicer cleaves longer strands of dsRNA into short dsRNA and makes staggered cuts that leave 3' overhangs (pronounced "3 prime overhangs") of about two base pairs—or two nucleotides—in length.

33. She identified this gene well before the RNA interference phenomenon ("RNAi") was demonstrated, and discovered that it has a dsRNA binding motif, two RNase III domains, and a helicase domain. She was the first to discover that this gene plays a role in dsRNA metabolism. A brief primer on RNAi is contained in a September 1, 2009 Memorandum and Order issued in the *Whitehead* litigation, beginning on page 3. (*See*, Exhibit 18.)

34. In 1994, Dr. Bass published a paper in the journal *Current Biology* characterizing proteins containing dsRNA binding motifs. In this paper, she noted that

K12H4.8 is a gene that produces a protein with a double-stranded RNA binding motif, as well as RNase III and helicase domains.

35. When RNAi was first reported by Drs. Fire and Mello in 1998, they were unable to describe the mechanism by which RNAi functioned in a cell. Dr. Bass soon recognized that the K12H4.8 gene she had discovered was likely to be involved in RNAi because of its unique structure, and began to consider its features. The fact that K12H4.8 had dsRNA binding motifs, RNase III domains, and a helicase domain led her to the conception that this enzyme catalyzed RNAi. In approximately 1998, she began developing experiments to test this conception. These experiments were carried out beginning in 1999.

36. Dr. Bass had members of her lab contact a *C. elegans* gene consortium to isolate *C. elegans* strains that contained a deletion mutation in the K12H4.8 gene. While waiting for this particular strain, she directed a member of her lab, Dr. Knight, to perform experiments to silence the expression of the Dicer gene using RNAi. This was a novel concept because it was not clear whether one could use RNAi to interfere with the RNAi function itself.

37. In early 2000, because of her extensive knowledge about dsRNA, the journal *Cell* asked Dr. Bass to write a review and comment on an article submitted by Tuschl, Zamore, and others called "RNAi: double-stranded RNA directs the ATP-dependent cleavage of mRNA at 21 to 23 nucleotide intervals" (the "Zamore Article"). The Zamore Article described the authors' discovery that a *Drosophila* lysate (in which they were studying RNAi) unexpectedly cleaved the long 500 base pair dsRNA they were

using to effect RNAi into short dsRNA of about 21-23 nucleotides. (*See*, Zamore Article, attached as Exhibit 4.)

38. The Zamore Article further indicated that one could effect RNAi by using the short dsRNAs isolated from the *Drosophila* lysate, although details of these experiments were not included.

39. Upon reading a pre-publication version of the Zamore Article in early March 2000, in preparation of her review and comment, Dr. Bass immediately recognized that the protein produced by the K12H4.8 gene had all of the properties necessary for RNAi, and that the resultant short dsRNA fragments would have a 3' overhang. On March 21, 2000 she began to draft her review, titled, "Double-Stranded RNA as a Template for Gene Silencing." (Published version attached as Exhibit 5.) As of March 21, 2000, her draft included information about RNAse III enzymes and specifically an RNAse III domain as part of the Dicer enzyme that cleaves dsRNA into short 21-23 nucleotide dsRNAs with 3' overhangs. (*See* Draft review attached as Exhibit 6.)

40. Dr. Bass' review, published April 28, 2000, set forth her conception that Dicer's RNAse III domains were responsible for cleaving dsRNA into approximately 23 nucleotide segments, and that it made staggered cuts that resulted in 3' overhangs. In her article she specifically identified the genes that encode Dicer in various organisms, such as *C. elegans*, *Drosophila*, and humans. Her review also set forth her conception that introducing dsRNA of about 21-23 nucleotides into a cell should trigger gene silencing, *i.e.*, that genetic disease could be treated in various organisms, including humans, by administering such molecules.

41. The Zamore Article eventually was published on March 31, 2000, and served as the basis for the Tuschl I provisional application No 60/193,594 (the "First Tuschl I Provisional"), filed with the USPTO on March 30, 2000—one week after Dr. Bass wrote her draft review. The named inventors in the First Tuschl I Provisional are Tuschl, Sharp, Bartel, and Zamore. (*See* First Tuschl I Provisional, attached as Exhibit 7.)

42. Neither the Zamore Article nor the First Tuschl I Provisional describes cleaving long dsRNA strands into short dsRNA of about 21-23 nucleotides connected to K12H4.8, an RNase III enzyme, or Dicer. Neither the Zamore Article nor the First Tuschl I Provisional describes that these short dsRNAs have a 3' overhang or the length of the overhang.

43. The named inventors of the Tuschl I Provisional admitted that they did not know how the short 21-23 nucleotide dsRNAs were produced in the drosophila lysate, and that they did not know the structure of those short dsRNAs. In the First Tuschl I Provisional, the inventors call the 21-23 nucleotide dsRNA "intriguing" and "curious." (Exhibit 7 at 36 11. 15-23.) They further admitted that "the significance of this finding [about the cleavage sites] is not understood." (*Id.* 36 11. 23.) Moreover, they make no mention of 3' overhangs or of Dicer.

44. The Tuschl I inventors simply did not know about the 3' overhangs when they filed the First Tuschl I Provisional, and only became aware of the 3' overhangs after Dr. Bass conveyed her concept to them, as discussed further in ¶¶ 48-50 and 54-57 below. Tuschl admitted that the importance of the 3' overhangs were not known to him until the Fall of 2000. (*See* Declaration of Thomas Tuschl at ¶¶ 18-24, attached as

Exhibit 8.) Moreover, as further discussed in ¶ 45 below, Tuschl and Zamore admitted on April 5, 2000, that they had no conception that Dicer cuts dsRNA into pieces 21-23 nucleotides long.

45. On April 5, 2000, Tuschl sent Zamore an email with the subject "Re: slide for banbury." (Attached as Exhibit 9.) This email was attached as Exhibit 20 in late 2010 to an affidavit in support of a motion filed in the *Whitehead* litigation, docket number 500. While the email was written before Dr. Bass' review was published, it is clear Tuschl and Zamore had seen a draft of the review. Significantly, Dr. Tuschl stated "i was not well informed on the typical product length generated by RNAse III degradation . . . ." (*Id.*) This email, containing Tuschl's admission that he and Zamore did not know on April 5, 2000 that Dicer (RNase III) cuts dsRNA into pieces 21-23 nucleotides long, was not known to Plaintiff until after November 28, 2010.

46. Prior to November 28, 2010, counsel for Plaintiff made oral and written requests of counsel for Alnylam and Max Planck (who have the same counsel), and the other Defendants, for information about this matter, and was refused. Moreover, a substantial portion of the documents, and the information contained therein, filed in the *Whitehead* litigation are filed under seal. The information about who was the first to conceive of the relevant inventions, and who contributed to the Tuschl II patent claims, was always in the possession of the Defendants, but not in the possession of the Plaintiff until after November 28, 2010.

47. Unlike Drs. Tuschl and Zamore, Dr. Bass had known all along that Dicer cuts dsRNA into 21-23 nucleotide pieces. This knowledge led her to the conception that Dicer catalyzed RNAi and that the critical short molecule would have a 3' overhang.

Without this information it would be impossible to synthesize the molecule that mediates RNAi. Synthesis is a key element of any commercial exploitation of RNAi.

48. On April 11, 2000, Dr. Bass presented her conception of 3' overhangs to a small group of RNA scientists at The Banbury Center, Cold Spring Harbor Laboratory (the "Banbury Conference"). The sole purpose of the invitation-only Banbury Conference was to provide a platform for collaboration, such as sharing of information and conceptions, amongst scientists studying "RNA Silencing: Functions, Mechanisms and Applications." ("RNA Silencing" is a synonym for RNAi.) Approximately 40 of the scientists central to the study of RNAi met at the Banbury Conference, including Drs. Bass and Zamore. Dr. Bass's presentation occurred during Session 4, "Biological and Molecular Approaches to Mechanisms." (*See* Banbury Conference Program, attached as Exhibit 10.)

49. To the Banbury Conference audience, Dr. Bass described her conception regarding Dicer's role in RNAi, including her conception that the short interfering RNA ("siRNA") would have 3' overhangs of about 2 nucleotides. (*See* slides used by Dr. Bass at the Banbury Conference, attached as Exhibit 11.)

50. Dr. Zamore attended Dr. Bass' presentation at the Banbury Conference, and an hour later Zamore presented on the Zamore Article, in the same collaborative Session 4 on "Biochemical and Molecular Approaches to Mechanism" as Dr. Bass. Drs. Zamore and Bass had known each other for years. It was common for Drs. Bass, Zamore, Tuschl, Bartel, and Sharp, all working on the same subject, at meetings such as the Banbury Conference, and others, to meet, collaborate, and share ideas. Dr. Bass attended meetings with these scientists and discussed her scientific work with them.

51. In May 2000, Dr. Bass' laboratory completed the experiments begun in 1999 to confirm her conception that Dicer was the enzyme behind RNAi. The experiments were successful and showed that RNAi does not occur in the absence of Dicer. (*See* Laboratory Notes, attached as Exhibit 12.)

52. As the attached Laboratory Notes demonstrate, Dr. Bass successfully used dsRNA to suppress the activity of the K12H4.8 gene in *C. elegans*. At Dr. Bass' direction, Dr. Knight injected dsRNA corresponding to the gene *fem-1* into *C. elegans* worms. When RNAi is functioning normally, as in a wild type worm, this causes *C. elegans*, which are hermaphrodites, to become abnormally "feminized." The experiments confirmed that worms remained hermaphrodites, and were not "feminized," when *fem-1* dsRNA was injected into worms also injected with dsRNA to the K12H4.8 gene. (*Id.*). This established that RNAi factors such as Dicer could be targeted by dsRNA and also that Dicer was essential for RNAi.

53. These successful experiments reduced to practice Dr. Bass' conception that Dicer was responsible for RNAi, and that therefore, short interfering dsRNA of about 21–23 nucleotides in length with 3' overhang were the mediators of RNAi in life and could be used to accomplish RNAi as a treatment for disease.

54. In August of 2000, Dr. Bass presented at a small meeting in Sandhamn, Sweden, called "The Uppsala BMC Summer Program 2000 Workshop on Chemical Biology." (*See* Uppsala BMC Summer Program 2000 program, attached as Exhibit 13.) The Uppsala Conference was an invitation-only platform for collaboration amongst leading RNA and RNAi scientists. Tuschl II inventors, Tuschl and Elbashir, attended this conference and each presented on aspects of RNAi, as did Dr. Bass.

55. Dr. Bass talked to Tuschl about her work at this meeting. She sat across from him during dinner and told him of the experiments performed in her laboratory, and that her lab had been successful in using RNAi to suppress RNAi components like Dicer by introducing dsRNA into *C. elegans*.

56. Drs. Bass, Zamore, Tuschl, Bartel, and Sharp all knew of each other's work. They collaborated by working to the same end—understanding the mechanism and structure of molecules that mediate RNAi. In the beginning of 2000, Dr. Bass conveyed to Zamore and Tuschl through several channels—including at least, the draft of her review, the Banbury Conference, and the Uppsala Workshop—her knowledge of the work they were doing, and her conception regarding Dicer, 3' overhangs, the length of the overhangs, the reduction to practice of her conceptions, and the results of those efforts.

57. Dr. Bass engaged with, and had an open line of communication with, Zamore and Tuschl through reviewing the Zamore article, their reading her review, and discussing with them at several conferences their work and her work, in a collaborative effort to share information to better understand RNAi. This line of communication was open during or at the approximate time of their alleged inventive effort.

58. In October 2000, two months after the Uppsala Workshop, Tuschl's lab submitted a paper to the journal *Genes and Development*, in which Elbashir stated that the most effective siRNAs are those that have 3' overhangs. (*See* RNA interference is mediated by 21- and 22-nucleotide RNAs, attached as Exhibit 14.) This paper cited Dr. Bass' review and her work on RNAse III (Dicer), (*id.* at 1, 10), and thanked Zamore, Bartel, and Sharp for their advice on the manuscript. (*Id.* at 14.) This *Genes &*

Development article is essentially the same as the disclosures of the Tuschl II family of patents.

The Tuschl Patents

59. On December 1, 2000, Tuschl and the other Tuschl II inventors filed a European Patent application known as EP 00126325.0, the priority document for all Tuschl II patents (the "EP Priority Document"). This filing was made unbeknownst to the other Tuschl I inventors. This application disclosed and claimed Dr. Bass' conception regarding 3' overhangs, and disclosed her conceptions relating to RNAse III, but failed to name her as an inventor, or the University as an owner. (*See* EP Priority Document, attached as Exhibit 15, at 1:24, 2:28-30; 3:16-30; 4:3-30; 6:5-8; 11:8-9; 12:6-10; 13:26-28; 19:21-22; 20:21-25; 22:5-29; 23:20-32; 24:4-7; 25:18-26:22; 27:4-8; 28:2-5; 38:8-11; 34:8-37:8 (claims 2-27); fig. 5A; fig. 7.)

60. On January 31, 2001, the Tuschl I inventors filed application No. 60/265,232 (the "Second Tuschl I Provisional"). The Second Tuschl I Provisional disclosed Dr. Bass' conception regarding 3' overhangs to support its claims to, *inter alia*, synthetic dsRNA that mediates RNAi. (*See* Second Tuschl I Provisional, attached as Exhibit 16 at 13:3-4; 15:28-16:2.) This application failed to name Dr. Bass as an inventor, even though it discloses and claims her inventive contributions.

61. On March 31, 2001, the Tuschl I inventors filed non-provisional application No. 09/821,832 (the "Tuschl I Non-Provisional"). Again, this application disclosed and claimed Dr. Bass' conception regarding 3' overhangs and RNAse III, but failed to name Dr. Bass as an inventor. (*See* Tuschl I Non-Provisional, attached as Exhibit 17 at Abstract; fig. 14b; [0005]; [0007]; [0008]; [0009]; [0043]; [0053]; [0054];

[0055]; [0056]; [0058]; [0145]; [0146]; [0147] (portions of specification using Dr. Bass' invention to support claims).)

62. No patent has yet issued on any of the Tuschl I applications. Dr. Bass should have been among the named inventors on the Tuschl I Non-Provisional application, because this application disclosed and claimed, as asserted by Whitehead and UMass in the *Whitehead* litigation, Dr. Bass' conception regarding 3' overhangs and RNAse III. As recently explained and clarified in *HIF Bio Inc., et al. v. Yung Shin, et al.*, 600 F3d 1347 (Fed. Cir. 2010), however, there is no private right of action in the patent law (e.g., under 35 U.S.C. § 116) to correct the inventorship of a pending patent application other than the Patent and Trademark Office's procedures under § 116. These procedures require the assent of all named inventors and owners of a pending patent application to effect a change of inventorship. None of the named inventors and owners have agreed to name Dr. Bass as the inventor or as an inventor of the Tuschl I applications. The University is, for the time being, without a cause of action to redress the Tuschl I erroneous inventorship until a Tuschl I patent issues. The University reserves its right to pursue any and all claims seeking to correct erroneous inventorship designations and for all damages caused to it because of the mischaracterization of inventorship.

63. Rights to the 3' overhangs were the central focus of a contentious litigation in this Court, the *Whitehead* litigation. A press release dated March 15, 2011, indicates that a settlement among the parties in the *Whitehead* litigation has been reached. That the 3' overhangs were the central focus of the litigation is evidenced by pleadings, letters, and affidavits filed in that case. (*See* Exhibit 18 at 6, 8, 11-12, 15-18, 21 (Judge's

order discussing the legal fight over who has the right to claim 3' overhangs); *see also* Exhibit 19 (letter discussing who has the right to claim 3' overhangs); Exhibit 20 (letter from counsel stating that "[c]laims containing the inventive subject matter of 3' overhangs were to be reserved for [Max Planck's] own patent [Tuschl II]]."); Exhibit 21 (email expressing a concern that the Tuschl I claims relied upon the Tuschl II EP Priority Document that contained 3' overhangs); Exhibit 22 (sworn affidavit testifying about an attempt by Tuschl I to claim the 2' overhang inventions of Tuschl II); Exhibit 23 (sworn affidavit testifying about the "Tuschl II proprietary technology referred to as the '3' Overhang'"); Exhibit 8 at ¶¶ 18-24 (sworn declaration of Dr. Tuschl in which he testifies to the importance of 3' overhangs); Exhibit 24 (sworn declaration testifying about "3' Overhang Disclosures"); Exhibit 25 (motion to reopen fact discovery to take Dr. Bass' deposition because "Dr. Brenda Bass . . . may be a proper inventor of the contested embodiment")).

64. Alnylam's Chief Executive Officer, John Maraganore, stated in 2009: "Alnylam has maintained an ongoing strategy to consolidate all the intellectual property required to develop and commercialize RNAi therapeutics." (Isis and Alnylam Announce Notice of Allowance for New U.S. Patent Application Broadly Covering RNAi Therapeutics, Bloomberg, December 15, 2009, attached as Exhibit 26.) The *Whitehead* litigation focuses almost exclusively on removing what is characterized as the "Tuschl II" information, "relating to 3' overhangs and RNAi in mammalian cells" from the Tuschl I materials, (Amended Complaint, *Whitehead* litigation, 09-cv-11116, document 152) presumably because its inclusion there dilutes the value of the Tuschl II Patents, the '704 and '196 Patents at issue here.

65. The claims of the Tuschl II Patents contain Dr. Bass' invention. This fact is admitted by Dr. Sharp in a 2001 *Genes & Development* article, "RNA interference," in which he wrote, "RNase III-type endonucleases cleave dsRNA releasing RNA with 2-nt 3' tails, indicating that this type of activity is probably involved in generating siRNAs (a possibility first suggested by Bass [2000])." (Exhibit 28 at 486.)

66. Alnylam has expressed extreme aggressiveness towards anyone who threatens its "consolidate all" RNAi strategy. (*See*, Plantiffs' Motion *in Limine* No.3 and Defendants' Opposition, filed in the *Whitehead* litigation, docket numbers 563 and 592.)

67. Mr. Maraganore's statement and the pleadings in the *Whitehead* litigation demonstrate that Dr. Bass' 3' overhang invention is the key—if not the only—patentable invention in the Tuschl II Patents, and the core technology required by the Alnylam business to consolidate and control RNAi therapeutics. The parties in the *Whitehead* litigation were fighting over who has the rights to Dr. Bass' invention.

68. Tuschl I cannot rely upon the First Tuschl I Provisional to support claims covering 3' overhangs. There is no written description of 3' overhangs in the First Tuschl I Provisional. Tuschl himself, having extraordinary skill in the art, testified that it would take "extraordinary efforts to isolate and characterize the sequences of small RNAs from an uncharacterized mixture of RNA fragments such as the one produced by the Drosophila lysate system." (Exhibit 8 at ¶ 23.) No person having only ordinary skill in the art, upon reading the specification for the First Tuschl I Provisional, would have been able to synthesize, enzymatically create, or isolate any dsRNA effective in mediating RNAi.

69. The claims of the Tuschl II ‘704 patent contain nothing that was new when the patent application was filed except Dr. Bass’ 3’ overhang and short overhang invention that Tuschl obtained from Dr. Bass’ draft *Cell* article, her Banbury Conference presentation, her *Cell* article, her Uppsala Workshop discussion with Tuschl, and from her discussions with Tuschl, Zamore and possibly others. For example, Claim 1 of ‘704 recites that it claims:

a) A method for making a piece of double stranded RNA with certain characteristics - making double stranded RNA was old and trivial at the time as admitted by the text of the Tuschl I application.

b) One characteristic of the molecule is that it mediates RNAi in mammals—that is taught by Dr. Bass’ *Cell* article, which specifically identifies the human gene for the Dicer enzyme and, hence, RNAi mediation in humans (a mammal) by a short dsRNA molecule with a short 3’ overhang. There is no evidence that Tuschl was independently aware of this fact except for Dr. Bass.

c) Another characteristic of the molecule is that it be 19-25 nucleotides long—Tuschl I and the Zamore Article had already described a length of 21-23 nucleotides.

d) Another characteristic is that the resultant molecule have at least one 3’ overhang with a short length of 1-5 nucleotides, exactly as conceived first by Dr. Bass and learned by Tuschl from her (3’ overhang of a length of 1-2 nucleotides).

70. Dr. Bass conceived first the only inventive elements of the claims of the Tuschl II ‘704 patent and, therefore, should be the only named inventor on that patent.

71. Similarly to the claims of the Tuschl II ‘704 patent, the Tuschl II ‘196 patent claims contain nothing new except for Dr. Bass’ first conception (taught to Dr. Tuschl) that the RNAi mediating molecule have a 3’ overhang of short length.

72. Dr. Bass conceived first the only inventive elements of the claims of the Tuschl II ‘196 patent and, therefore, should be the only named inventor on that patent.

73. Plaintiff has demanded that Defendants name Dr. Bass as the sole or joint inventor on the ‘704 and ‘196 Patents, or other patents and patent applications claiming her inventions, and Defendants have refused.

74. The Tuschl II Patents and applications are of great value to the Defendants. The Tuschl II Patents at issue here are central and crucial to the Alnylam United States patent estate and a chief source of the value of the company and the income it has generated. Not only are the Tuschl II Patents based on Dr. Bass' invention in each of the three core United States categories of Alnylam's patent estate by Alnylam's own admission (“Fundamental Patents,” “Chemistry and Delivery Patents,” “Target Patents”), they are the important technology in each category. (*See* Printout from Alnylam’s website, attached as Exhibit 27 .)

75. In each category of the U.S. Alnylam patent estate, the patents are listed alphabetically by named inventor. No significance can be given to the order in which they are listed.

76. The Alnylam U.S. "Fundamental Patents" category includes work by three others—Crooke, Fire and Mello, and Woppman. The Woppman piece is not an issued patent but merely a pending patent application.

77. The Fire and Mello patent is the work of the Nobel laureates who discovered that the RNAi phenomenon existed in multicellular organisms and could be applied outside of plants. The patent, however, has claims that are limited to methods of inhibiting expression of a target gene in invertebrates and cells *in vitro*. The Fire and Mello patent is not commercially pertinent to treatment of disease in humans, which is the principle source of Alnylam revenue.

78. The three Crooke patents all derive from the same work. They relate to oligomeric compounds, such as Tuschl II's basic 3' overhang compounds, with modifications and methods of using the same. The Crooke patents are not as significant as Tuschl II's basic 3' overhang claims that Tuschl obtained from Dr. Bass' conception. The Crooke technology is of little value unless one knows what molecule to apply it to. The key structure of that molecule is Dr. Bass' invention.

79. The patents listed under U.S. "Chemistry and Delivery Patents" are related to types of modifications that can be made to oligomeric compounds, such as Tuschl II's basic 3' overhang compounds, and delivery systems or modifications that can be used to enhance the activity of Tuschl II's basic 3' overhang compounds. This technology is of little value unless one knows what molecule to apply it to. The key structure of that molecule is Dr. Bass' invention. The "Chemistry and Delivery Patents" patents are not as significant as Tuschl II's basic 3' overhang claims which Tuschl got from Dr. Bass' conception.

80. Alnylam's U.S. "Target Patents" category only contains one patent - the Tuschl II '704 patent, in which every claim recites Dr. Bass' invention of short 3' overhang.

81. Similarly, Max Planck's website touts its ownership of the Tuschl II Patents.

82. Two patents were filed in Europe, EP 1407044 Tuschl II and EP 1309726 Tuschl II, based on the original U.S. Tuschl II application. Max Planck had no right to file these applications because they had no right to the claimed subject matter. These patents have generated revenue for Defendants that would not have been earned if not for the 3' overhang material conceived of by Dr. Bass.

83. The Tuschl II Patents, and all related applications and patents with the same priority—the Tuschl II Patent Family—have generated hundreds of millions of dollars of revenue for Defendants.

84. On information and belief, the Defendants own or control other patents or patent applications that claim Dr. Bass' invention in whole or in part. Dr. Bass should be named the sole inventor or an inventor, and the University should be the sole owner or an owner of these patents and patent applications that claim the 3' overhang.

COUNT I
Correction of Inventorship under 35 U.S.C. § 256 on U.S. Patent No. 7,056,704 – Against all Defendants (Dr. Bass as Sole Inventor)

85. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

86. Dr. Bass is the sole inventor of all the claims of the '704 Patent.

87. Through omission, inadvertence, and/or error, Dr. Bass was not listed on the ‘704 Patent as the inventor of all the inventions claimed in the ‘704 Patent.

88. The omission of Dr. Bass as the inventor on the ‘704 Patent occurred without any deceptive intent on the part of Dr. Bass.

COUNT II
In the Alternative:
Correction of Inventorship under 35 U.S.C. § 256 on
U.S. Patent No. 7,056,704 – Against all Defendants
(Dr. Bass as Joint Inventor)

89. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

90. Dr. Bass is a joint inventor all the claims of the ‘704 Patent.

91. Through omission, inadvertence, and/or error, Dr. Bass was not listed on the ‘704 Patent as a joint inventor of the inventions claimed in the ‘704 Patent.

92. The omission of Dr. Bass as a joint inventor on the ‘704 Patent occurred without any deceptive intent on the part of Dr. Bass.

COUNT III
Correction of Inventorship under 35 U.S.C. § 256 on
U.S. Patent No. 7,078,196 – Against all Defendants
(Dr. Bass as Sole Inventor)

93. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

94. Dr. Bass is the sole inventor of all the claims of the ‘196 Patent.

95. Through omission, inadvertence, and/or error, Dr. Bass was not listed on the ‘196 Patent as the inventor of the inventions claimed in the ‘196 Patent.

96. The omission of Dr. Bass as the inventor on the ‘196 Patent occurred without any deceptive intent on the part of Dr. Bass.

COUNT IV
In the Alternative: Correction of Inventorship under 35 U.S.C. § 256 on U.S. Patent No. 7,078,196 – Against all Defendants (Dr. Bass as Joint Inventor)

97. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

98. Dr. Bass is a joint inventor all the claims of the ‘196 Patent.

99. Through omission, inadvertence, and/or error, Dr. Bass was not listed on the ‘196 Patent as a joint inventor of the inventions claimed in the ‘196 Patent.

100. The omission of Dr. Bass as a joint inventor on the ‘196 Patent occurred without any deceptive intent on the part of Dr. Bass.

COUNT V
Declaratory Judgment Under 28 U.S.C. §§ 2201 and 2202 – Against all Defendants

101. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

102. Dr. Bass is the sole or a joint inventor of the ‘704 and ‘196 Patents, the claimed inventions of which were conceived by Dr. Bass.

103. Dr. Bass is not listed as the inventor or a joint inventor of the ‘704 or ‘106 Patents.

104. An actual, present, and justiciable controversy has arisen concerning the inventorship of the ‘704 and ‘196 Patents.

105. Plaintiff seeks declaratory judgment from this Court that Dr. Bass is the sole or a joint inventor of the ‘704 and ‘196 Patents, and any other patents owned or controlled by Defendants of which Dr. Bass is the inventor or an inventor, and any injunctive relief necessary to enforce its rights under that declaratory judgment.

COUNT VI
Conversion – Against Max Planck and Alnylam

106. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

107. Plaintiff owns the intellectual property and the intellectual property rights of Dr. Bass, including the right to any patents based on her intellectual property and to any patent documents (including assignment documents), U.S. and foreign, claiming those rights.

108. Max Planck and Alnylam have wrongfully exercised dominion over the property of Plaintiff either through accepting the assignment of rights under the '704 and '196, by licensing those rights, by purchasing the rights, by claiming the rights to the '704 and '196 Patents as part of their intellectual property estate, and refusing to name Dr. Bass as either the sole or joint inventor of the '704 and '196 Patents, and other patents and patent applications claiming her inventions.

109. As a direct and proximate result of Max Planck and Alnylam's conversion of Plaintiff's property, Plaintiff has suffered, and will continue to suffer harm and substantial damages in the form of loss of value of the patents and the revenues derived from licenses to that property.

COUNT VII
Replevin – Against Max Planck and Alynylam

110. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

111. Plaintiff owns the rights to Dr. Bass' intellectual property and the intellectual property rights of Dr. Bass, including the right to any patents based on her intellectual property and to any patent documents (including assignment documents), U.S. and foreign, claiming those rights. claiming those rights.

112. Plaintiff has demanded that Max Planck and Alnylam name Dr. Bass as the sole or joint inventor on the '704 and '196 Patents, and other patents and patent applications claiming her inventions, and Max Planck and Alnylam have failed, refused, and neglected to do so.

113. Plaintiff's rights to Dr. Bass' intellectual property and the intellectual property rights, including the right to any patents based on her intellectual property and to any patent documents (including assignment documents), U.S. and foreign, of Dr. Bass are superior to the rights of Max Planck and Alnylam, and Plaintiff is entitled to immediate possession.

114. By virtue of the foregoing acts, conduct, and omissions of Max Planck and Alnylam, Plaintiff is entitled to take immediate possession of Dr. Bass' intellectual property and the intellectual property rights, including the right to any patents based on her intellectual property and to any patent documents (including assignment documents), U.S. and foreign, of Dr. Bass.

115. As a direct and proximate result of Max Planck and Alynylam's wrongful detention of Plaintiff's property, Plaintiff has suffered, and will continue to suffer harm and substantial damages in the form of loss of value of the patents and the revenues derived from licenses to that property.

COUNT VIII
Unjust Enrichment – Against Max Planck and Alnylam

116. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

117. Plaintiff conferred a benefit on Max Planck and Alnylam by providing them valuable intellectual property through Dr. Bass.

118. Max Planck and Alnylam accepted and retained Plaintiff's valuable intellectual property, and used the intellectual property to their own advantage, at Plaintiff's expense.

119. Max Planck and Alnylam have been and continue to be unjustly enriched by profiting from the wrongful conduct described in this Complaint. In particular, Max Planck and Alnylam have made wrongful use of Plaintiff's property by asserting inventorship, refusing to name Dr. Bass as either the sole or a joint inventor, and deriving an unjust benefit from licensing these property rights and from commercially exploiting Dr. Bass' inventions. It would be inequitable for Max Planck and Alnylam to retain these benefits under these circumstances.

120. Plaintiff has incurred, and continues to incur detriment in the form of loss of money and property as a result of Max Planck and Alnylam's wrongful use of Dr. Bass' intellectual property and intellectual property rights, including the right to any patent based on her intellectual property and to any patent documents (including assignment documents), U.S. and foreign that belong to Plaintiff. The intellectual property and the intellectual property rights, including the right to any patents based on Dr. Bass' inventions and to any patent documents (including assignment documents), U.S. and foreign, are unique and there is no adequate remedy at law.

121. The harm to Plaintiff is and continues to be substantial and irreparable.

COUNT IX
Common Law Unfair Competition – Against Max Planck and Alnylam

122. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

123. Max Planck and Alnylam have represented and continue to represent to the public that they developed and own the intellectual property that they wrongfully appropriated without Plaintiff's authorization and consent.

124. In so doing, Max Planck and Alnylam are passing off Plaintiff's intellectual property as their own in violation of the common law.

125. Plaintiff is informed and believes, and thereupon alleges, that Max Planck and Alnylam's wrongful passing off of Plaintiff's intellectual property as their own has caused, and will cause, consumer confusion, and has been a substantial factor in directly and proximately causing damages and irreparable harm to Plaintiff.

COUNT X
False Advertising in Violation of Mass. Gen. Laws c. 266, § 91 – Against Max Planck and Alnylam

126. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

127. By reason of their wrongful conduct, including, but not limited to, promoting and advertising Plaintiff's intellectual property as their own on their website and elsewhere, Max Planck and Alnylam violated Massachusetts General Laws c. 266, § 91.

128. Max Planck and Alnylam's wrongful conduct is a substantial factor in directly and proximately causing damages and irreparable harm to Plaintiff, and Plaintiff will continue to be harmed so long as Defendants' wrongful conduct continues.

COUNT XI
Violation of Mass. Gen. Laws c. 93A § 11 – Against Max Planck and Alnylam

129. Plaintiff hereby realleges and incorporates by reference the foregoing paragraphs of the Complaint as if fully set forth herein.

130. At all relevant times, Plaintiff and Max Planck and Alnylam were engaged in trade or commerce within the meaning of Massachusetts General Laws. c. 93A, §§ 1 and 11.

131. Max Planck and Alnylam's unfair acts and practices pursuant to Massachusetts General Laws. c. 93A include, without limitation, unjust enrichment and conversion, as set forth in this Complaint.

132. The wrongful actions described herein were willful and knowing.

133. As a direct and proximate result of the foregoing knowing and/or willful unfair acts and practices of Max Planck and Alnylam, Plaintiff has suffered and will continue to suffer significant harm in the form of loss of money or property, including but not limited to, the loss of value of the rights to any patents based on Dr. Bass' intellectual property and to any patent documents (including assignment documents), U.S. and foreign, and the revenues derived from licenses to that property.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff request that the Court grant the following relief:

A Judgment in Plaintiff's favor on each count;

B Order the USPTO to correct the inventorship on U.S. Patent No 7,056,704 to name Dr. Bass sole inventor, or in the alternative as a joint inventor;

C Alternatively, order the Defendants to sign the requisite documents to correct the inventorship on U.S. Patent No 7,056,704 to name Dr. Bass sole inventor, or in the alternative as a joint inventor;

D Order the USPTO to correct the inventorship on U.S. Patent No 7,078,196 to name Dr. Bass sole inventor, or in the alternative as a joint inventor;

E Alternatively, order the Defendants to sign the requisite documents to correct the inventorship on U.S. Patent No 7,078,196 to name Dr. Bass sole inventor, or in the alternative as a joint inventor;

F Issue a declaratory judgment naming Dr. Bass as sole inventor, or in the alternative as a joint inventor, of U.S. Patent Nos. 7,056,704 and 7,078,196 as requested herein;

G Issue a declaratory judgment naming Dr. Bass as sole inventor, or in the alternative as joint inventor, of all other U.S. and foreign patents and patent applications in which the 3' overhang is claimed, and all order assignment of all right title and interest in all such other U.S. and foreign patents and patent applications to Plaintiff;

H Pursuant to 28 U.S.C. § 2202, issue any injunctions necessary to enforce the declaratory judgment naming Dr. Bass as sole inventor, or in the alternative as a joint inventor, of U.S. Patent Nos. 7,056,704 and 7,078,196, and all other U.S. and foreign patents and patent applications in which the 3' overhang is claimed, and order assignment of all right title and interest in U.S. Patent Nos. 7,056,704 and 7,078,196, and all other U.S. and foreign patents and patent applications to Plaintiff;

I Order Max Planck and Alnylam to disgorge to Plaintiff all monies and/or profits derived from the wrongful conduct alleged herein;

J An award to Plaintiff of the amount by which Max Planck and Alnylam have been unjustly enriched;

K Award appropriate royalties for Defendants' use of Plaintiff's intellectual property;

L Order an accounting of any monetary or other benefits received by Max Planck and Alnylam as a result of their wrongful conduct;

M Order a constructive trust over all information, patent applications, patents, technology, products, and other materials in the possession, custody, or control of Max Planck or Alnylam that wrongfully constitute, contain, were based on, and/or derived in whole or in part from the use of Plaintiff's intellectual property, and an order that Max Planck or Alnylam immediately transfer to Plaintiff all right, title, and interest in such information, patent applications, patents, material, technology, and products;

N Award money damages to Plaintiff against Max Planck and Alnylam;

O Award treble damages for Max Planck and Alnylam's willful and knowing violations of Mass. Gen. Laws c. 93A;

P Award prejudgment interest according to proof;

Q Award Plaintiff's reasonable costs and attorneys' fees; and

R Award such other and further relief, including equitable relief, as this Court may deem just and proper.

University of Utah

By its attorneys,

/s/ Russell J. Barron

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